

What is claimed is:

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1 1. A vascular or endoluminal stent adapted for deployment in a vessel or
2 tract of a patient to maintain an open lumen therein, comprising a biocompatible hollow tube
3 with a multiplicity of openings through an open-ended tubular wall thereof, said openings being
4 shaped according to a plurality of serpentine elements within at least a substantial portion of
5 said wall and running circumferentially in juxtaposed substantially sine wave-like patterns, each
6 of uniform multiple cycles, wherein adjacent ones of said patterns are offset from each other
7 by a predetermined phase difference at interconnecting points therebetween about the
8 circumference of the tubular wall and are uniformly displaced longitudinally along an axis of
the tube, said tube constituting a single member from which the entire stent is fabricated.

1 2. The stent of claim 1, wherein the phase difference at the interconnecting
2 points between adjacent longitudinally-displaced ones of said sine wave-like patterns of the
3 serpentine elements is 180° , and each of said interconnecting points includes means for
4 enhancing symmetric expansion of the stent when subjected to relatively uniform radial
outwardly-directed forces exerted from within said tube.

1 3. The stent of claim 1, wherein the interconnecting points between said
2 patterns of the serpentine elements are notched circumferentially to enable firm crimping of the
3 stent upon a balloon when positioned in an axial lumen of the stent, and to enhance symmetric

expansion of the stent upon inflation of the balloon for deployment of the stent.

1 4. The stent of claim 1, wherein each of the serpentine elements has a rounded cross-section.

5. The stent of claim 4, wherein said cross-section is oval.

1 6. The stent of claim 1, wherein the uniform longitudinal displacement of
2 the circumferential substantially sine wave-like patterns is interrupted at least once along the
3 axis of the stent by transversely oriented serpentine elements that run longitudinally within said
4 wall in juxtaposed at least partial substantially sine wave-like patterns having openings through
5 the wall which are shaped according to the transversely oriented serpentine elements, adjacent
6 ones of the transverse patterns being offset from each other by a 180° cyclical phase difference
7 at interconnecting points therebetween along the axis of the tube, said transversely oriented
8 serpentine elements being adapted to maintain the length of said tube substantially invariant
with radial expansion of the stent.

1 7. The stent of claim 1, wherein the tube, as structured with said serpentine elements and openings, is annealed.

1 8. The stent of claim 1, wherein the annealed tube has longitudinally

tapered ends.

1 **9.** The stent of claim 1, wherein the wall of the tube is laser cut, whereby
said openings and serpentine elements are cleanly formed therein.

1 **10.** The stent of claim 1, wherein said tube has an original diameter and is
2 expandable to a fully deployed second larger diameter upon radial expansion thereof, and is
3 adapted for symmetric expansion of the stent by having been pre-opened to a third diameter
intermediate the original and second diameters.

1 **11.** The stent of claim 1, wherein said tube has substantially rounded
surfaces throughout.

1 **12.** The stent of claim 3, wherein said tube has substantially rounded
surfaces throughout, except at the notched points.

1 **13.** The stent of claim 1, wherein said tube includes means for maintaining
the length of said tube substantially invariant during radial expansion of the stent.

1 **14.** The stent of claim 1, further including an expansion balloon inserted into
2 the axial lumen of the tube, and having proximal and distal ends extending beyond proximal and

3 distal ends of the stent when the stent is affixed to the balloon by partial inflation thereof, and
4 a catheter shaft connected to the proximal end of the balloon and having a lumen for inflation
5 thereof, whereby to enable advancement of the stent on the partially inflated balloon in a vessel
6 or tract of the patient to a predetermined site and deployment of the stent by further inflation
of the balloon at said site.

1 15. The stent of claim 1, wherein said tube is mechanically biased to
2 substantially reduce inertial forces thereof needed to be overcome to enable substantially
symmetrical expansion of the stent during deployment thereof.

1 16. A vascular or endoluminal stent adapted for deployment in a vessel or
2 tract of a patient to maintain an open lumen therein, comprising a metal open-ended tube, a
3 multiplicity of through holes in the wall of said tube encompassed by serpentines that constitute
4 said wall, the serpentines extending sinusoidally each in multiple 360° wavelengths in a single
5 turn about the axis of the tube and juxtaposed in plural substantially identical segments
6 disposed with regularity along the axis, each segment having a length equal to the distance
7 between crests and troughs of the sinusoid, adjacent serpentines being joined together at crest
8 and trough, respectively, whereby the serpentines are interconnected 180° out of phase relative
9 to the wavelength of the immediately adjacent sinusoid, said tube being the single component
10 of the stent and the serpentines and interconnections thereof being shaped throughout for
optimum uniform expansion of the stent during deployment thereof.

1 **17.** The stent of claim 16, wherein the shaping of the interconnections
2 between adjacent serpentines includes a notch substantially symmetrically located at either side
 of the junction of the respective crest and trough.

1 **18.** The stent of claim 17, wherein the serpentines are substantially devoid
 of sharp corners and edges, except at the notches.

19. The stent of claim 16, wherein each serpentine has an oval cross-section.

1 **20.** The stent of claim 16, wherein the regularity of the segments is
2 interrupted at least once along the axis of the tube by serpentine means for maintaining the
3 length of the tube substantially invariant despite radial expansion of the stent during
 deployment.

1 **21.** The stent of claim 16, wherein the serpentines in the tube are pre-
2 stressed before deployment of the stent to ease the deployment and enhance substantially
 symmetrical radial expansion of the stent.

1 **22.** The stent of claim 21, wherein the pre-stressed serpentined tube is
 annealed.

23. The stent of claim 16, wherein the tube is annealed.

1 24. The stent of claim 16, wherein the exterior surface of the tube wall is longitudinally tapered to be of smaller diameter at its ends than at its mid-point.

1 25. The stent of claim 16, wherein the openings and serpentines are laser-cut.

1 26. The stent of claim 22, wherein the openings and serpentines are laser-cut.

1 27. The stent of claim 26, wherein said tube has substantially rounded surfaces throughout.

1 28. A process for fabricating a vascular or endoluminal stent adapted for
2 deployment in a vessel or tract of a patient to maintain an open lumen therein, comprising the
3 step of laser cutting a biocompatible hollow tube to form a multiplicity of openings through an
4 open-ended tubular wall thereof while simultaneously forming a plurality of serpentine elements
5 in the wall running circumferentially therein in juxtaposed substantially sine wave patterns of
6 uniform multiple wavelengths, with adjacent ones of said patterns offset from each other by

7 180° relative to their wavelengths at interconnecting points therebetween about the
8 circumference of the tubular wall and arranged in uniform longitudinally displaced segments
along the axis of the tube.

1 29. The process of claim 28, further including circumferentially notching the
2 interconnecting points between said substantially sine wave patterns of the serpentine elements
3 to enhance symmetric expansion of the stent upon inflation of a balloon within a lumen along
the axis of the stent.

1 30. The process of claim 28, including the step of notching interconnecting
2 points between said substantially sine wave patterns of the serpentine elements to enable firm
crimping of the stent upon a balloon within a lumen along the axis of the stent.

1 31. The process of claim 28, including the step of rounding sharp edges and
corners of each of the serpentine elements and their interconnections.

1 32. The process of claim 31, wherein said step of rounding is performed by
electro machining said tube.

1 33. The process of claim 28, including the step of interrupting the
2 longitudinal segments in which the substantially sine wave patterns are lying, at least once along

3 the axis of the tube by laser cutting transversely oriented serpentine elements in the wall that
4 run longitudinally in at least partial substantially sine wave patterns and juxtaposed
5 circumferentially, while simultaneously cutting openings of said transversely oriented serpentine
6 elements through the wall, and with adjacent ones of the transversely oriented patterns being
7 offset from each other by 180° relative to their wavelengths at interconnecting points
8 therebetween along the axis of the tube, so that said transversely oriented serpentine elements
9 will act to maintain the length of said tube substantially invariant with radial expansion of the
stent.

1 34. The process of claim 28, further including the step of annealing the tube
after said serpentine elements and openings are cut therein.

1 35. The process of claim 34, further including the step of polishing the
annealed tube to longitudinally taper the ends thereof.

1 36. The process of claim 28, including the step of radially pre-opening the
2 tube from its original diameter before the laser cutting step to a diameter intermediate the
3 original diameter and the radially expanded diameter at which the stent is fully deployed, to
4 ease expanding the stent at the time of deployment thereof and enhance symmetric expansion
of the stent.

1 37. A process for providing a vascular or endoluminal stent adapted for
2 deployment in a vessel or tract of a patient to provide an open lumen therein, comprising the
3 steps of directing a narrow laser beam of sufficient intensity onto the wall of a biocompatible
4 metallic tubular element to cut openings through the wall which form a remaining continuous
5 metal serpentine pattern having the tubular shape of the element; rounding sharp edges and
6 corners in said pattern to produce a substantially oval cross-section therein between adjacent
7 openings; and breaking the continuity of the pattern in at least one predetermined location
8 therein to inhibit longitudinal shortening of the tubular shape during radial expansion thereof
when deployed in the vessel or tract.

1 38. The process of claim 37, further including annealing the metal serpentine
pattern after said rounding step.

1 39. The process of claim 37, wherein said rounding step is an electro
2 machining method in which the stent as developed is subjected to an electrolytic current of
sufficient magnitude to produce said rounding of the corner and edges.

1 40. The process of claim 38, wherein said annealing is performed after pre-
2 opening the stent by radial expansion thereof to a diameter considerably smaller than the
3 diameter to which the stent will be opened when fully deployed in a vessel or tract of the
patient, to produce a symmetric expansion of the stent during deployment thereof.

1 **41.** The process of claim 40, further including, after the pre-opening,
crimping the stent on an expansion balloon to be used during deployment .

1 **42.** The process of claim 41, further including inflating the balloon to a
2 pressure in the range from 0.1 to 0.5 atmospheres, to partly open the balloon at its distal and
3 proximal ends which extend beyond the respective distal and proximal ends of the stent crimped
4 on the balloon, whereby to retain the crimped stent firmly in place on the balloon and create
5 a cushion for protecting the stent and preventing it from contacting tissue during advancement
through the vessel or tract to a site at which the balloon is to be deployed.

1 **43.** A method of deploying a vascular or endoluminal stent in a vessel or
2 tract in the body of a patient, which comprises inflating an expansion balloon without the stent
3 thereon to a pressure in a range from about 0.1 to about 0.5 atmosphere to partially inflate the
4 balloon, advancing the partially inflated balloon over a guidewire to a predetermined site of the
5 vessel or tract where the stent is to be deployed by radial expansion thereof, and retracting the
6 balloon in an uninflated state, whereby to ascertain that the passageway through the vessel or
7 tract will accommodate advancement of a stent crimped on a similar balloon inflated to
substantially the same pressure to said predetermined site.

1 **44.** The method of claim 43, further including the step, after retracting the
2 balloon, of crimping a stent on an expansion balloon substantially identical to the retracted

balloon, partially inflating the balloon sufficiently to distend proximal and distal ends thereof extending beyond respective ends of the crimped stent without substantially expanding the stent diameter, and thereafter advancing the expansion balloon with the stent crimped thereon to said predetermined site for deployment of the stent.

45. A stent for vascular or endoluminal implantation, comprising a substantially continuous serpentine structure having elements of substantially oval cross-section winding in a periodically joined pattern defining a multiplicity of holes in a regular repeated pattern in a wall of an open-ended biocompatible metal tube, for radial expansion from a first production diameter to a fully deployed second diameter, and adapted for symmetric expansion by having been pre-opened to a third diameter intermediate the first and second diameters.

46. The stent of claim 45, wherein said structure is annealed in the pre-opened state.

47. The stent of claim 45, wherein said structure includes an extension of a different pattern that acts to maintain the original length of the stent during the radial expansion thereof.

48. A process of fabricating a vascular or endoluminal stent adapted for deployment in a vessel or tract of a patient to maintain an open lumen therein, said process

3 comprising cutting through a metal open-ended tube in a predetermined manner to form a
4 multiplicity of through holes in the wall of said tube encompassed by serpentes that constitute
5 said wall, so that the serpentes extend sinusoidally each in multiple 360° wavelengths in a
6 single turn about the axis of the tube and juxtaposed in plural substantially identical segments
7 disposed with regularity along the axis, each segment having a length equal to the distance
8 between crests and troughs of the sinusoid, adjacent serpentes being joined together at crest
9 and trough, respectively, whereby the serpentes are interconnected 180° out of phase relative
10 to their wavelength, said tube being the single component of the stent; and shaping the
11 serpentes and interconnections thereof throughout the tube for optimum uniform expansion
of the stent during deployment thereof.

1 **49.** The process of claim 48, wherein the step of shaping the
2 interconnections between adjacent serpentes includes providing a notch substantially
symmetrically located at either side of the junction of the respective crest and trough.

1 **50.** The process of claim 49, including electro machining the stent to provide
serpentes substantially devoid of sharp corners and edges, except at the notches.

1 **51.** The process of claim 50, including fabricating each serpentine to
provide an oval cross-section thereof.

1 **52.** The method of claim 48, including interrupting the regularity of the
2 segment at least once along the axis of the tube by serpentine means for maintaining the length
of the tube substantially invariant despite radial expansion of the stent during deployment.

1 **53.** The method of claim 48, including the step of pre-stressing the
2 serpentines in the tube before deployment of the stent to ease the deployment and enhance
substantially symmetrical radial expansion thereof.

1 **54.** The method of claim 53, further including the step of annealing the pre-
stressed serpentine tube.

55. The method of claim 48, including the step of annealing the tube.

1 **56.** The method of claim 48, including the step of longitudinally tapering the
exterior surface of the tube wall to be of smaller diameter at its ends than at its mid-point.

1 **57.** The method of claim 48, including the step of laser cutting the openings
and serpentines.

1 **58.** The method of claim 52, including the step of cutting the openings and
serpentines with a laser.

1 **59.** The stent of claim 1, wherein the phase difference at the interconnecting
2 points between adjacent longitudinally-displaced ones of said sine wave-like patterns of the
3 serpentine elements is 180° relative to each other, and is less than 180° relative to the 360°
4 circumference of the tube and the number of sine wave-like cycles in each of said
circumferential patterns.

1 **60.** A method of producing an expandable stent, the method including the
2 steps of cutting openings through the wall of a hollow tube, and tapering the thickness of the
3 wall of the tube by removing material circumferentially from the external surface of the tube
4 in progressively greater amounts from a point between the midpoint and an end of the tube to
said end, whereby to render the stent easier to advance through the human vascular system.

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